This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Penny Greco
Philips Ultrasound, Inc.
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810-6302
Tel: (978) 659-4615
Fax (978) 975-7324

Date prepared: May 23, 2011

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic ultrasound system and transducers

Proprietary Name: CX50 Diagnostic Ultrasound System

Classification Name: Class II

21 CFR Section	Classification Name	Product Code
892.1550	System, Imaging, Pulsed Doppler, Ultrasonic	90 IYN
892.1560	System, Imaging, Pulsed Echo, Ultrasonic	90 IYO
892.1570	Transducer, Ultrasonic, diagnostic	90 ITX

3) Substantially Equivalent Devices

CX50 Diagnostic Ultrasound System	K091804 / K081802
HD11 Diagnostic Ultrasound System	K043535

3) Device Description

The CX50 Diagnostic Ultrasound System is a compact, AC or battery powered, 128 – channel, cardiac ultrasound imaging. It uses custom digital electronic and fabrication technologies to provide diagnostic ultrasound information and is housed in a portable, laptop-style chassis. The only changes made in this CX50 510(k) are the additional indications of Cardiac Pediatric and Neonatal Cephalic. There are no new or unique features/technical characteristics introduced with the addition of the new indications.

Cardiac Pediatric and Neonatal Cephalic indications have been previously cleared for other Philips Ultrasound systems, including the predicate device, HD11 Ultrasound system (K043535). This modification to the CX50 involves only the two new indications, as reflected in labeling.

4) Intended Use

The CX50 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical –mode), Pulse Wave Doppler, continuous Wave Doppler, color Doppler, tissue Doppler Imaging and Harmonics (Tissue and contrast) modes. The device is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Musculo-skeletal, Gynecological, Cardiac Adult, Cardiac pediatric, Trans-Esoph. (Cardiac), Peripheral Vessel, Other (Carotid)

5) Technological comparison to predicate devices

Philips CX50 and HD11 Diagnostic Ultrasound are Track 3 systems that employ the same fundamental scientific technology.

6) Determination of Substantial Equivalence

Non-clinical performance data
No new hazards were identified with the addition of cardiac pediatric and neonatal cephalic indications. No new testing was required to determine safety and efficacy of the CX50 with the new indications.

Summary of Clinical Tests
The CX50 required no modifications to support the neonatal cephalic and cardiac pediatric indications. The clinical safety and effectiveness of the system and transducers were identified in previous CX50 submissions (K091804 and K081802). The clinical safety and effectiveness of the Neonatal Cephalic and Cardiac Pediatric indications are well accepted for use with ultrasound systems including the predicate device, Philips HD11 (K043535).

7) Conclusions

CX50 with additional indications is substantially equivalent in safety and effectiveness to the predicate identified above:

- The predicate devices and CX50 with additional indications are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The predicate devices and CX50 with additional indications have the same gray-scale and Doppler capabilities.
- The predicate devices and CX50 with additional indications use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate devices and CX50 with additional indications have acoustic output levels below the Track 3 FDA limits.
- The predicate devices and CX50 with additional indications are manufactured under equivalent quality systems.
- The predicate devices and CX50 with additional indications are manufactured of materials with equivalent bio safety. The materials have been evaluated and found to be safe for this application.
- The predicate devices and CX50 with additional indications are designed and manufactured to the same electrical and physical safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 2 4 2011

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO NY 55313

Re: K111513
Trade/Device Name: Philips CX50 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 31, 2011
Received: June 1, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Philips CX50 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

S5-1
L12-3
C9-3v
C5-1
D5-cwc
D2cwc
X7-2t

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K111513

Device Name: Philips CX50 Diagnostic Ultrasound System

Philips CX50 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Fetal
Abdominal
Pediatric
Small Organ
Adult Cephalic
Neonatal Cephalic
Trans-vaginal
Musculo-skeletal
Gynecological
Cardiac Adult
Cardiac Pediatric
Trans-Esoph. (Cardiac)
Peripheral Vessel
Other (Carotid)

The clinical environments where the CX50 Diagnostic Ultrasound System can be used include point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	P	P	P		P	P	P (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric	P	P	P	P	P	P	P (1,3-8)
	Abdominal	P	P	P	P	P	P	P (1,3-9)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	P	P	P		P	P	P (1,3-8)
	Neonatal Cephalic	N	N	N	N	N	N	N(1-8)
	Adult Cephalic	P	P	P	P	P	P	P (1,3-7)
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P	P (1,3-8)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	P	P	P		P	P	P (1,3-8)
	Musculo-skel (superficial)	P	P	P		P	P	P (1,3-8)
	Other (Gynecological)	P	P	P		P	P	P (1,3-9)
Cardiac	Cardiac Adult	P	P	P	P	P	P	P(1-4)
	Cardiac Pediatric	N	N	N	N	N	N	N (1-7)
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P(1-4)
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P (1,3-8)
	Other (Carotid)	P	P	P		P	P	P (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue or Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K091804 for 2.0 release of CS50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: S5-1 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	P	P	P		P	P	P (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	N	N	N	N	N	N	N (1-8)
	Adult Cephalic	P	P	P	P	P	P	P (1,3-7)
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	N	N	N	N	N	N	N (1-7)
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes:	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D (Freedhand) Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K091804 – use of S5-1 transducer with the 2.0 release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: L12-3 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	P	P	P		P	P	P (1,3-8)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	P	P	P		P	P	P (1,3-8)
	Musculo-skel (superficial)	P	P	P		P	P	P (1,3-8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P (1,3-8)
	Other (Carotid)	P	P	P		P	P	P (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D (Freedhand) Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K091804- use of L12-3 transducer with the 2.0 release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: C9-3v transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	P	P	P		P	P	P (1,3-8)
	Abdominal	P	P	P		P	P	P (1,3-9)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P	P (1,3-9)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	P	P	P		P	P	P (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K091804 – use of C9-3v transducer with the 2.0 release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: C5-1 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	P	P	P		P	P	P (1,3-8)
	Abdominal	P	P	P		P	P	P (1,3-9)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P (1,3-9)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)	P	P	P		P	P	P (1,3-8)
	Other (Gynecological)	P	P	P		P	P	P (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P (1,3-8)
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D (Freedhand) Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K091804- use of C5-1 transducer with the 2.0 release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: D5cwc transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric				N			N (1-7)
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel				P			
	Other (Carotid)				P			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K091804- use of D5cwc transducer with the 2.0 release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111513

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111573

Device name: D2cwc transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				N			N (1-7)
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

* Other modes:
Combined modes:
Previous submission: K081802– use of D2cwc transducer with the first release of CX50

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111573

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K111513

Device name: X7-2t transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

* Other modes: Harmonics (Tissue & Contrast), Tissue Doppler Imaging
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: K081802– use of X7-2t transducer with the first release of CX50

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111513